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**OFFICE OF NEW ANIMAL DRUG EVALUATION**
**REVIEWERS' CHAPTER**

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# FREEDOM OF INFORMATION (FOI) SUMMARY FOR A NEW ANIMAL DRUG APPLICATION (NADA)



## I. PURPOSE

To describe a standardized format for the Freedom of Information Summary for an approved New Animal Drug Application under 21 CFR 514.11(e)(2). [1]

## II. PROCEDURE TO FOLLOW

Under 21 CFR 514.11(e), a summary of the safety and effectiveness data and information submitted or incorporated by reference must be prepared for an approved NADA. CVM may require the sponsor to prepare a summary of such data and information, which will be reviewed and revised as appropriate by CVM. Alternatively, CVM may prepare its own summary. The CVM reviewer should write the Agency Conclusions section of the FOI Summary. The reviewer should follow the procedures in the guide to ensure that the FOI summary contains necessary information in a consistent format.

In addition to the paper copy, the sponsor should submit the draft FOI Summary in an electronically compatible format (MSWORD preferred). If the sponsor has not done so, the primary reviewer should request it electronically (filed as an

[1] In 1985, CVM issued a revised FOI Summary guideline. That guideline needs to be revised, but does contain some useful information. The reviewer should follow the procedures and format outlined in this P&P guide where this guide does not match the 1985 guideline. If the reviewer has questions on any discrepancies, they should consult with their Team Leader or Division Director.

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Responsible Office: ONADE Quality Assurance Team (HFV-102).
Date: 11/16/2001

amendment). The electronic format allows corrections and additions to be made quickly and efficiently during the final review process, especially during processing of the approval package.

For supplemental applications, the unaffected sections of the summary should refer (by date) to the FOI summary for the original or a previous supplemental approval, as appropriate; for example, "This approval does not affect this section of the summary. Refer to FOI summary dated *<date.>*"

The following illustrates the format that should be used for an FOI summary:

## III. FORMAT FOR NADA FOI SUMMARY

Each FOI summary should include a cover sheet that provides the following information: drug name, proprietary name, file number, sponsor name, general description of approval (species, dose), and date of approval. Reviewers, at their discretion, can include a table of contents.

### *1. GENERAL INFORMATION:*

| | |
|---|---|
| a. File Number: | *<insert file number e.g., NADA xxx-xxx>* |
| b. Sponsor: | *<insert company name>*<br>*<insert company address>*<br>Drug Labeler Code: *<insert code number from 21 CFR 510.600>* |
| c. Established Name: | *<insert drug's established name>* |
| d. Proprietary Name: | *<insert product's proprietary name>* |
| e. Dosage Form: | *<insert dosage form>* |
| f. How Supplied: | *<insert how supplied>* |
| g. How Dispensed: | *<insert Rx, OTC, or VFD>* |

| | | |
|---|---|---|
| h. | Amount of Active Ingredients: | *<insert the amount of active ingredient>* |
| i. | Route of Administration: | *<insert route of administration>* |
| j. | Species/Class: | *<insert species/class>* |
| k. | Recommended Dosage: | *<insert recommended dosage>* |
| l. | Pharmacological Category: | *<insert pharmacological category>* |
| m. | Indications: | *<insert indication(s) verbatim from label>* |

*If the summary is for a supplemental approval, include:*

| | | |
|---|---|---|
| n. | Effect of Supplement: | *<insert effect of the action>* |

***2. EFFECTIVENESS:***

***a. Dosage Characterization:***
*<Provide a justification and characterization of the critical aspects of the dose-response relationship relevant to the dose or dose range selected.>*

***b. Substantial Evidence:***
*<Provide a complete description of each pivotal effectiveness study in its own separately headed section. The description should provide a full identification of the study including name of clinical investigator, location of study, brief outline of the protocol, number of animals, and study results. The best way to provide study results may be in tabular format.>*

***3. TARGET ANIMAL SAFETY:***

*<Provide a complete description of all studies used to form a decision on the safety of the drug to the target species. List each study individually with all identification information: name of study director, location of study, brief outline of the protocol, number of animals, GLP compliance statement, and study results.*

***4. HUMAN SAFETY:***

a. *If the product is to be used in a non-food producing animal, include the following language:*

This drug is intended for use in *<insert non-food species,>* which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Not for human use. Keep this and all drugs out of the reach of children." *<Insert any additional human warnings as deemed appropriate. Provide a complete description of the user safety concerns including steps for amelioration.>*

b. *If the product is to be used in a food-producing animal, include the nine sections provided below. Provide the rationale for any sections that are not considered appropriate for this approval.*

- **Toxicity:**
  *<Each study should be individually listed with all identification information: title of study, name of study director, location of study, brief outline of the protocol, number of animals, GLP compliance statement, and study results.>*

- **Safe Concentration of Total Residues – Determination of No Observed Effect Level (NOEL):**
  *<Provide a complete description of the determination of NOEL, including proper citation to all referred data.>*

- **Safe Concentration of Total Residues – Calculation of the Acceptable Daily Intake (ADI) and the Safe Concentration (SC):**
  *<Provide a schematic of the calculation of the ADI and the SC.>*

- **Total Residue Depletion and Metabolism Studies:**
  *<Each study should be individually listed with all identification information: title of study, name of study director, location of study, brief outline of the protocol, number of animals, GLP compliance statement, and study results. >*

- **Comparative Metabolism Studies:**
  *<Each study should be individually listed with all identification information: title of study, name of study director, location of study, brief outline of the protocol, number of animals, GLP compliance statement, and study results. >*

- **Residue Depletion Studies:**
  *<Each study should be individually listed with all identification information: title of study, name of study director, location of study, brief outline of the protocol, number of animals, GLP compliance statement, and study results.>*

- **Tolerance and Withdrawal Time:**
  *<Provide a complete description of the considerations in assigning or not assigning a tolerance and withdrawal time. Cite appropriate studies.>*

- **Regulatory Method for Residues:**
  *<If a tolerance is assigned, provide a brief description and location of the analytical method for residues.>*

- **User Safety Concerns:**
  *<Provide a complete description of the user safety concerns including steps for amelioration.>*

## *5. AGENCY CONCLUSIONS:*

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrates that *<insert product name,>* when administered *<insert criteria,>* is safe and effective for *<insert claim.>*

*<Provide a detailed discussion of the decision on the marketing status (Rx vs. OTC), a summary paragraph on human safety concerns, and a statement on analytical methodology (if required).>*

*If an exclusivity period is applicable, use the following language:*

*Note whether exclusivity was granted or not. Also include the citation for the section of the Federal Food, Drug, and Cosmetic Act (the Act) that provides for exclusivity (512(c)(2)(F)(i), 512(c)(2)(F)(ii), 512(c)(2)(F)(iii), or 512(c)(2)(F)(v)) and note the duration. The examples of common exclusivity situations and the paragraphs used are described in Guide 1243.5780 (www.fda.gov/cvm/index/policy_proced/ppindex.html). If exclusivity is granted, note the basis on which exclusivity was granted (i.e., what studies should be included in the MRA).*

*If a supplemental application, the reviewer should describe the type of action, e.g. a category I or II.*

*Provide available Patent Information (as submitted by the Sponsor):*
*<Drug Name>* is under the following U.S. patent numbers:

| U.S. Patent Number | Date of Expiration |
|---|---|
| XXXXXXXX | *<insert date>* |

***6. ATTACHMENTS:***

Facsimile Labeling is attached as indicated below:
*List which types of labeling are attached.*

## IV. DISTRIBUTION COPIES FOR NADA FOI SUMMARY

Copies should be distributed as follows:

cc: Courtesy copy for the sponsor (no *cc:block* listed on this copy)
HFV-199, NADA Orig. [white copy]
HFV-2, Special Mailing List
HFV-12, FOI Staff (no *cc:block* listed on this copy)
HFV-102, Reserve Copy
HFV-102, Green Book
HFV-120, Labeling Project
HFA-305, Dockets Management Branch (no *cc:block* listed on this copy)
HFR-XXxxx, District Office Copy

Name of Primary Reviewer

*<Author's name, HFV-#, date>*

**NOTES:**
Reviewers should send forward only one copy of the FOI Summary with the draft Approval Package.

A copy should be provided to the FDA DO for a sponsor's headquarters and for any FDA DOs identified in the HFV-140 Technical Section Complete letter or Manufacturing Chemistry Review Memoranda (as indicated in the *cc: block*). Guidance on FDA DOs is provided in CVM POLICY AND PROCEDURES Guide 1243.3300, Copies of Correspondence to FDA District Offices: www.fda.gov/cvm/index/policy_proced/ppindex.html

The reviewer should provide all necessary copies in the final approval package. Copies are designate for distribution on the cover page (upper right hand corner).